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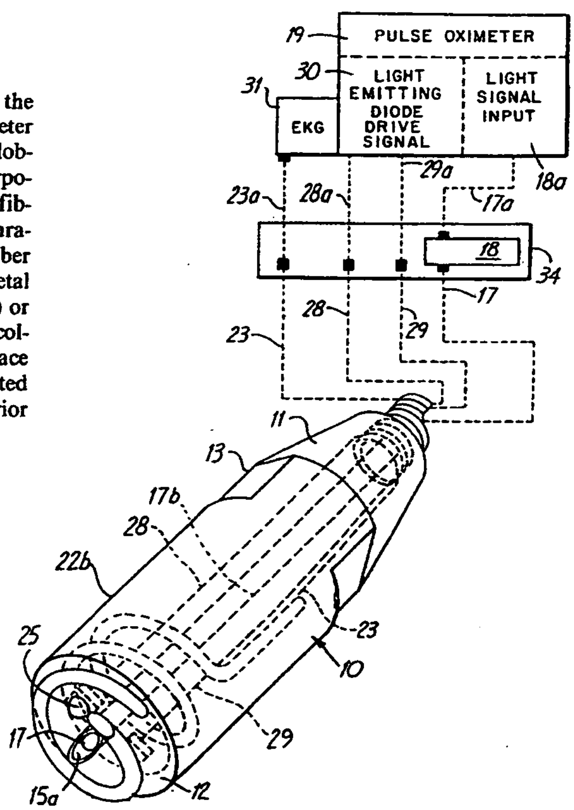
(54) Title: FETAL PROBE APPARATUS

(57) Abstract

Disclosed is a fetal probe (10) that is insertable through the mother's vagina and cervix and connectable to a pulse oximeter (19) for monitoring the EKG and oxygen saturation of hemoglobin of a fetus during labor and delivery. The probe (10) incorporates at least one spiral electrode (22) and optical fiber (17) or fibers and/or solid state light sources for monitoring oxygen saturation. Light emitting diodes (25, 27), or an optical fiber or fiber pair, transmit light of two different wavelengths through the fetal skin to perfused fetal tissue while either the EKG needle (22) or another needle extends into fetal tissue and contains a light collecting optical fiber (17) having a distal light collecting surface adjacent the relative needle distal end for collecting transmitted light that has passed through perfused fetal tissue that is interior of the fetal skin.



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FETAL PROBE APPARATUS

FIELD OF THE INVENTION

The invention relates to apparatus for monitoring oxygen saturation of functional arterial hemoglobin and monitoring EKG of a fetus during labor and delivery.

BACKGROUND OF THE INVENTION

Monitoring of fetal heart rate trends through the use of an EKG electrode has long been used as a indicator of fetal well-being during labor and delivery. Increased awareness of serious adverse short and long term effects of fetal oxygen starvation (hypoxia) has resulted in a significant increase in the number of babies being monitored in this manner during birth.

Interpretation of heart rate trends in the fetal EKG record is subjective and a skill which requires substantial experience to acquire and maintain and has not been consistently reliable, especially in settings away from the high maternity rate urban areas.

In interpreting heart rate trends in the fetal EKG record, the physician attempts to infer the adequacy of oxygenation in the fetus. This technique is thus indirect and less than satisfactory since it is only after oxygen starvation has been occurring for some time that it is reflected in the EKG record. Also, the record itself is subject to non-deleterious phenomena such as uterine contractions. It is estimated that errors in interpretation of heart rate trends currently yields 50% false positives (conclusion that fetal distress is present when it is actually not) and 20% false negatives (instances where fetal distress is present but was not recognized).

There is an important difference in oximetry and pulse oximetry, oximetry referring to a general measurement of oxygenation of blood and tissue. In contrast pulse oximetry is an established method of

determining in real time the relative oxygen saturation of arterial hemoglobin, and is used routinely in surgical suites and intensive care environments. Pulse oximetry provides an immediate and objective measure of oxygenation and requires little technical knowledge or interpretive expertise for its application.

In the opinion of some fetal physiology experts pulse oximetry is a superior technique for monitoring fetal status than pH since pulse oximetry provides real time monitoring of oxygen sufficiency and immediate corrective measures can be taken. If such insufficiency has persisted long enough for it to be reflected by a lower pH, it is likely that some neurological damage has already occurred.

U.S. Patent 4,294,258 to Bernard discloses a measuring head for measuring an ionic or physico-chemical activity, notably pH in a part of, for example, the head of an unborn infant. The Figure 15 embodiment includes a pair of hollow spiral claws. One of the claws contains a diaphragm sensitive to ionic activity while the second claw contains an extension of a KCL electrode.

Hochberg et al U.S. Patent 4,658,825 discloses a fetal probe having a single spiral needle containing a pair of optical fibers that are connected to a light source and light sensor exterior of the probe for monitoring EKG and a select chemical condition such as pH. Alternately a second spiral needle could be provided with one needle being used for pH and the other for EKG. The fiber pair carries light to and from the interior of the needle to detect color changes in a pH sensitive dye within the needle, it being stated that body fluids are allowed through a window in the needle and to an ion permeable dye containing membrane within the needle and adjacent to the needle distal end. There is no indication that the light is ever intended to leave through the window.

The Hochberg probe and other probes use pH as an indicator to imply an insufficient oxygen supply, this method being indirect. The logic used is that if the pH has decreased (become acidic), then the concentration of CO_2 has increased. If the concentration of the CO_2 is too high, then circulation/exchange at the placenta is compromised. If that is true, then oxygen supply is also likely insufficient.

Hon U.S. Patent 4,321,931 and Reissue 28,990 disclose a conducting helix used as an electrode for use in monitoring fetal EKG.

U.S. Patent 4,281,645 to Jobsis discloses a non-invasive structure and procedure for monitoring a state of metabolic activity in a body organ. That is, this patent is directed to the use of the optical characteristics of the enzyme cytochrome A to monitor cellular oxidative metabolism within an organ such as the heart, brain, or kidney by passing multiple wavelengths of visible and infrared light through the organ. The transmitters are being indicated as being on one side of the organ and the receivers on the opposite side of the organ, for example opposite sides of the head or chest.

Hulka U.S. Patent 4,537,197 discloses a fetal probe having a suction cup with a first aperture opening through its inner surface through which light from an optical fiber is transmitted to the fetal brain and an adjacent aperture through which the transmitted light is returned through an optical fiber. The light is to penetrate the skull to a depth where enzymatic activity associated with normal oxygenation in brain cells will be evident.

U.S. Patent 3,973,555 to Moller discloses an electric cell assembly having an electrode that can be introduced and anchored in the living tissue of a fetus. The assembly is for measuring pH and includes a spiral to anchor the device.

Farrar et al U.S. Patent 4,281,659 disclose a probe for fetal monitoring. The disclosure is primarily directed to pH, however it is indicated that the arrangement is compatible with other measuring functions such as fetal ECG, pO_2 etc. The probe includes a base that threadingly mounts a probe and two spiral electrodes that serve to hold the base in place on the fetal skull.

Aaronoudse, J.G. "Subcutaneous Oxygen Tension In the Fetal Scalp During Labour Continuous Monitoring With A Needle Electrode", British Journal of Obstetrics and Gynaecology, 1981: 88: 517, discloses a pair of spirals for attaching the assembly to a fetal skull and generally straight oxygen needle for measuring subcutaneous Po_2.

Takayama U.S. Patent 3,822,695 discloses a catheter system for simultaneously obtaining measurements of the blood pressure and the percentage content of oxygen contained in the blood within a blood vessel by inserting one end of an optical fiber bundle within a catheter into the blood vessel. Infrared rays and red light are passed through a catheter and there is individual detection of the amount of light reflected from the carboxyhemoglobin and oxyhemoglobin.

Isaacson U.S. Patent 4,773,422 discloses pulse oximeter apparatus for non-invasively measuring and indicating the percentage level of various constituents in arterial blood. Light of a plurality of separate wavelengths is sequentially passed through a portion of the body.

In order to overcome problems encountered with various types of prior art probes and to provide improved apparatus to simultaneously monitor fetal EKG and directly measure arterial hemoglobin oxygen saturation of a fetus during labor and delivery using techniques of pulse oximetry, this invention has been made.

SUMMARY OF THE DISCLOSURE

The pulse oximetry fetal probe apparatus includes a probe body having a distal end, at least one needle spirally extending distally of the body, at least one of the needles being spiral and at least one optical fiber that extends within the distal end portion of the above needle or a second needle to receive light and carry the light signals back to a pulse oximeter external of the human body, and a light transmitter that is connected to the pulse oximeter and emits a light signal either adjacent to the external surface of the skin of a fetus or penetrates the skin of the fetus. A needle serves as an EKG electrode. The light transmitter may be a fiber or a pair of optical fibers that transmit two different wavelengths of light or a pair of light emitting diodes.

The probe includes optical fibers and/or solid state light sources (light emitting diodes) to permit the optical measurement of the oxygen saturation of fetal hemoglobin. The optical geometry of the probe is such that only optical signals which are derived from modulation by pulsatile variations in capillary blood volume of light which has been transmitted through perfused fetal tissue are analyzed and interference from light reflected from the surface of the fetal skin is excluded. In the event diodes are used, advantageously one emits a visible wavelength (red) and the other infrared.

Although it is satisfactory that the light transmitting distal surface be at the skin surface, it is preferred that the light collection distal surface be internally of the skin since light entering the monitor detector via a different path (i.e., not perfused tissue) can very easily seriously contaminate the measurement. A key consideration is that skin penetration ensures that the optical path be confined to perfused tissue.

One of the objects of this invention is to

provide new and novel probe means for monitoring a chemical condition of the blood during labor and delivery. A further object of this invention is to provide new and novel means for determining a real time relative oxygen saturation of arterial hemoglobin. Another object of this invention is to provide new and novel means usable with a conventional pulse oximeter monitor for transmitting a light signal to be scattered, reflected, absorbed and returned to the monitor light detector through a needle that penetrates the fetal skin. An additional object of the invention is to provide new and novel means to directly measure the oxygenation sufficiency of the arterial blood supply to ensure that an adequate supply of oxygen is being delivered.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of the first embodiment of the probe of this invention;

Figure 2 is a distal end view of the first embodiment of the probe;

Figure 3 is a somewhat diagrammatic section view of the first embodiment;

Figure 4 is a fragmentary cross sectional view of the straight needle of the first embodiment;

Figure 5 is a perspective view of the second embodiment of the invention;

Figure 6 is for the most part a cross sectional view of the second embodiment;

Figure 7 is a distal end view of the second embodiment;

Figure 8 is a fragmentary perspective distal end view of the third embodiment;

Figure 9 is a distal end view of the third embodiment;

Figure 10 is a fragmentary view of the distal end portion of the spiral needle of the third embodiment;

Figure 11 is a fragmentary perspective distal

end view of the fourth embodiment;

Figure 12 is a distal end view of the fourth embodiment;

Figure 13 is a fragmentary cross sectional view of the distal end portion of the probe body of the fourth embodiment to show the optical fibers, one being flush with the distal surface of the probe body and the other being extending within the spiral needle;

Figure 14 is a fragmentary perspective distal end view of the fifth embodiment;

Figure 15 is a distal end view of the fifth embodiment;

Figure 16 is a fragmentary cross sectional view of the distal end portion of one of the spiral needles; and

Figure 17 is a fragmentary cross sectional view of the distal end portion of the other of the spiral needles.

Referring to Figures 1-4, the first embodiment of the probe of this invention, generally designated 10, includes a probe body 11, advantageously made of injection molded high density polystyrene or other biologically compatible material, that has a distal end surface 12. The major axial part of the body is cylindrical and has proximal flats 13 for facilitating the use of the probe.

A straight, hollow needle 15 extends axially beyond the distal end of the probe body and has a distal sharpened edge 15a distally inwardly of the body surface 12. An optical, light receiving fiber (light collector) 17 has its distal end radially adjacent the needle sharpened edge 15a and a proximal end connected to an adaptor 34 which incorporates an optical detector 18 whose output is electrically connected by a line 17a to the light (optical) signal input 18a of a conventional pulse oximeter monitor 19, for example one sold by Nonin

Medical, Inc. of Plymouth, Minnesota, USA.

An EKG needle 22 has a proximal portion embedded in the probe body, the needle 22 including a spiral portion 22b that in part is embedded in the probe body while the remainder, including its distal sharpened end 22a, extending distally away from the body surface 12. The needle may be solid or tubular. The needle spiral portion exterior of the probe body extends through about 3/4 to 1 1/2 turns. A lead 23 electrically connects the EKG needle to the adaptor 34 and thence through line 23a to the EKG terminal of the EKG monitor 31. The central axis of the spiral portion 22b and the central axis of the straight needle that are in radial adjacent relationship to one another are coextensive.

A first and a second light emitting diode (light transmitters) 25, 27 respectively are at least partially embedded in the distal end portion of the probe body on diametrically (transverse) opposite sides of the straight needle 15 and in radial spaced relationship to the straight needle 15, but adjacent thereto. The light emitting portions (light transmittal distal surfaces) of the diodes either extend slightly distally away from the surface 12 or are located proximally closely adjacent to the surface 12 and the light is emitted through apertures in the probe body. Diode 25 emits visible red (for example about 660 nm) while diode 27 emits infrared (for example about 920 nm). Conduits 28 and 29 are respectively connected to diodes 25 and 27 and the adaptor and thence through lines 28a and 29a to the source portion 30 of the monitor. The light emitting diodes are connected in parallel, but with opposite polarity (cathode-anode and anode-cathode) so that the wire pair 28, 29 can drive them alternately using pulses of opposite polarity.

Advantageously the leads 23, 28, 29 from within the probe body adjacent to the proximal end of the probe

body to the adaptor 34 may be coiled in a triple filar manner about the radial adjacent parts of the optical fiber 17. Preferably the straight needle terminates axial intermediate the distal and proximal ends of the probe body. Advantageously, the distal terminal end of the fiber insulation 17b (thickness of insulation relative to rest of fiber being exaggerated) of the fiber 17 terminates adjacent to the proximal end of the needle 15 while the non-insulated portion extends within the needle 15 as indicated above. The probe is a disposable item. If the monitor is of a type that includes the facility to monitor EKG, then a separate EKG monitor 31 would not be required.

In use, the probe is rotated to attach the probe head to the fetal scalp with at least the diodes abutting against the fetal head skin surface if they extend distally of the surface 12, otherwise the surface 12 abuts against the skin, and the light is emitted at the skin surface to penetrate the skin and the perfused tissue below the skin where the light is scattered, reflected, and absorbed and modulated by the pulsatile varying capillary blood volume.

At this time the straight needle 15 penetrates the fetal tissue a few millimeters below the skin. The fiber in the needle 15 serves to collect the modulated light and a light (optical) signal is returned to the light signal input portion 18a of the monitor 19 that is external of the mother and the probe body. The proximity of the diodes relative to the straight needle ensures that the infrared and visible optical paths are similar. The light in traveling from the diodes passes through the skin and adjacent tissues to the distal tip of the fiber 17 in needle 15 where the light is collected and returned to the detector 18. Both the visible and the infrared signals experience similar optical modulations with one exception. The visible signal experiences an additional

absorption which is principally a function of the relative oxygen saturation of the arterial hemoglobin in the optical path.

Both the visible and infrared signals from the detector vary as a function of probe placement, skin pigmentation, fetal motion, and other factors in an unpredictable manner. However, both signals experience similar variations with the exception of the visible absorption due to varying oxygen saturation. Thus, by using the infrared signal as a reference, monitoring the visible signal permits the determination of arterial oxygen saturation for the fetus. Additionally, since both signals vary with each fetal heart beat, the fetal heart rate is directly obtained. This permits direct comparison with the heart rate as monitored with standard fetal EKG methods.

Even though the needle 15 has been described and shown as having its proximal end terminating within the probe body, it is to be understood that needle 15 may have its proximal end terminating proximally outwardly of the probe body.

Referring to Figures 5-7, the second embodiment of the probe of this invention, generally designated 37, is substantially the same as the first embodiment other than it contains a single package of two light emitting diodes (light transmitters having distal light transmitting terminal surfaces) 38, 39 that function the same as diodes 25, 27 respectively, but are located on the same radial side of the straight hollow needle 15, and additionally includes a second EKG needle 40 in addition to the EKG needle 41 that is the same as needle 22. Thus the EKG needles form a double spiral and have their sharpened ends 40a, 41a respectively substantially diametrically opposite one another on transverse opposite sides of the needle 15. As illustrated the needles 40, 41 are of shorter spiral lengths than the needle 22. The

lead 44 electrically connects the proximal end portions of the spiral needles to one another and extends outwardly of the probe body for direct or indirect (through adaptor 34) connection to the EKG monitor. Further leads 28, 29 connect the diodes directly to the pulse oximeter 19, or indirectly to the oximeter 19 in the same manner indicated for the first embodiment.

It is noted that the first embodiment of the probe may be modified by having the diodes 25, 27 located in a single package on one transverse side of the straight needle such as the situation with the second embodiment and/or provided with a second spiral needle.

Referring now to Figures 8-10, the third embodiment of the probe of this invention, generally designated 50, includes a probe body 51, a straight needle 52 and an optical fiber 53 that are substantially the same as the corresponding numbers 11, 15, 17 of the first embodiment and function in the same manner. Further the probe 50 includes an EKG needle 55 that includes a spiral portion extending distally of the distal transverse surface 54 of the probe body. However, the needle 55 is hollow to have the light transmitting optical fibers 57, 58 extend therethrough to terminate just short of the distalmost part of the sharpened edge 55a of the needle. The fiber 57 transmits the visible wavelength light while the fiber 58 transmits the infrared light to the distal terminal end of the needle 55.

The manner of use of the third embodiment is substantially the same as that of the first embodiment other than that the two wavelengths are transmitted from the monitor or adaptor through the respective optical fiber pair 57, 58. It is to be noted that the optical fibers 57, 58 may be in part located in the needle 52 instead of the needle 55, and if so the optical fiber 53 in part would be located in the needle 55.

Advantageously a single fiber may be used in place of fibers 57, 58 to perform the same functions.

Referring to Figures 11-13, the fourth embodiment of the probe of this invention, generally designated 70, includes a probe body 71, a hollow EKG needle 72 that at least external of the body is spiral, and an optical fiber (light collector) 74 that extends distally adjacent to the distal sharpened edge 72a of the needle and is connected to the adaptor as is the EKG needle. Further the probe 70 includes a light transmitting optical fiber pair 78a, 78b having their distal ends substantially flush with the distal transverse surface 75 of the probe body and extending generally coextensive with the central axis of the radially adjacent part of the spiral portion of the EKG needle that is within the probe body. The fiber pair 78a, 78b may be located within a tube 79 that has its distal terminate end flush with the surface 75. The fiber 78a transmits visible wavelength light adjacent to surface 75 while fiber 78b transmits infrared wavelength light. Even though a fiber pair has been used, it is to be understood that a single fiber or fiber bundle that performs the same functions may be substituted for fibers 78a, 78b.

Referring to Figures 14-17, the fifth embodiment of the probe of this invention, generally designated 80, includes a probe body 81, a hollow EKG needle 82 and a light collecting optical fiber 85 extending within needle 82 that, other than for the angular spiral dimension of the exterior portion of needle 82, are substantially the same as the corresponding members of the third embodiment and function in the same manner. Further the probe 80 includes a hollow second needle 84 having a spiral portion that extends at least distally of the body distal transverse surface 88. The second needle exterior spiral

portion has its central axis coextensive with the central axis of the corresponding portion of the needle 82, and of the same external spiral dimension, but has its sharpened terminal edge 84a diametrically opposite the central axes from that of the corresponding edge 82a of needle 82. A light transmitting optical fiber (light transmitter) 83 extends within the needle 84 and has its distal terminal end adjacent to the sharpened edge 84a while the distal terminal end of the fiber (light collector) 85 terminates adjacent to the sharpened edge 82a. The fiber 83 performs the same functions as fibers 57, 58 of the third embodiment. The needle 84 may or may not be electrically connected to the needle 82.

With reference to teach of the third, fourth and fifth embodiments the optical fibers and EKG electrode are connected to the EKG and pulse oximeter monitor in a manner similar to the first embodiment and are used in a manner similar to that described with reference to the first embodiment.

Even though the exterior parts of the spiral portion of the needles having spiral needles of the first, third and fourth embodiments are shown as extending angularly a little less than one complete turn; and those of second and fifth embodiments are shown as extending angularly a little more than 180•, it is to be understood that advantageously the exterior spiral portion may extend through about 3/4 to 1 1/2 turns.

In each of the embodiments the light collecting fiber is located beneath the skin surface even though in some of the embodiments the light transmitter distal surface is at the skin surface (exterior of the skin surface). That is, at least the distal terminal surface of the light collector is internal to the fetal scalp while the distal terminal surface of the light transmitter may be internal or external of the fetal scalp. Further the entry point of the light collector

distal terminal surface is significantly spaced from the light transmitter distal terminal surface to ensure that the optical path is confined to perfused tissue. This eliminates a major source of error in oximetry measurement and one which continues to be a problem in external oximeter probes (neonatal and others). Also with reference to measuring EKG, a second electrode (not shown) may be mounted by the probe body or attached to the mother in a conventional manner.

Even though not preferred, it is to be understood the embodiments may be modified to have their light transmitting distal end surfaces interchanged with the light collector distal end surface including the respective light transmitter and collector members. Further if only one light transmitting figure is used instead of two, the single fiber would alternately transmit infrared and red wavelength pulses.

Thus there is disclosed herein pulse oximeter EKG apparatus that includes a fetal probe for insertion through the mother's vagina and cervix.

At least each of the straight needles of the first three embodiments and the needles of the fourth and fifth embodiments have hollow tubular portions within the probe body with at least one optical fiber extending therein.

For those embodiments which do not include light emitting diodes within the distal portion of the probe body, it is to be understood that suitable solid state light source and/or detectors may be located within the adaptor and/or the pulse oximeter with their optical inputs and/or outputs connected by means of optical fiber or fibers to the distal portion of the fetal probe (the respective distal end portion of the needle and/or distal surface of the probe body).

WHAT IS CLAIMED IS:

1. Fetal probe monitoring apparatus for continuously monitoring a constituent of arterial blood of a fetus during labor and delivery, comprising a fetal probe having a longitudinal central axis and a distal end surface, first means mounted by the probe body for penetrating the fetal skin and at least in part removably attaching the body to the fetus, the first means including a first needle mounted by the probe body to extend distally of the body distal surface, the first needle having a distal terminal end portion that has an opening to open to fetal tissue inwardly of fetal skin and into perfused fetal tissue, second means having a distal light collecting surface for collecting light after the light has passed through the adjacent perfused fetal tissue, third light means having a distal light transmitting surface for transmitting light to pass through the skin surface and perfused fetal tissue and then to the second means collecting surface, one of the second and third means extending within the needle to have its distal surface adjacent to the needle opening to have the respective one of the collected light and transmitted light pass through the needle opening and the other having its distal surface exterior of the needle and spaced from the needle sufficiently that light in being transmitted has to travel through perfused tissue prior to being collected, each of the second and third means at least in part extending within the probe body and adjacent to the body distal surface.

2. The apparatus of claim 1 further characterized in that the light transmitting means includes fourth and fifth means for transmitting visible light and infrared wavelength respectively.

3. The apparatus of claim 2 further characterized

in that the needle comprises an EKG monitoring needle.

4. The apparatus of claim 1, comprising a pulse oximeter having means for providing a light source of visible and infrared light signals to the light transmitting means and light receiving means for receiving collected light from the light collecting means for determining the oxygen saturation of arterial hemoglobin.

5. The apparatus of claim 4 further characterized in that the light transmitting means comprises first and second diodes to emit visible and infrared light respectively, the diodes having the light transmitting surfaces exterior of the fetal skin when the body is attached to the fetus and adjacent to the body distal surface to transmit light through the fetal skin.

6. The apparatus of claim 5 further characterized in that the first needle has distal linear portion extending distally of the body surface and having a central axis at least substantially coextensive with the body central axis, the diodes being generally located on diametric opposite sides of the linear portion and transversely spaced from the linear portion.

7. The apparatus of claim 5 further characterized in that the first needle has distal linear portion extending distally of the body surface and having a central axis at least substantially coextensive with the body central axis, the diodes being located on the same side of the linear portion and transversely spaced from the linear portion.

8. The apparatus of claim 5 further characterized in that the light collecting means comprises an optical

fiber extending within the first needle and having the light collecting distal surface.

9. The apparatus of claim 5 further characterized in that first means comprises a second needle mounted by the probe body and having a spiral portion extending distally of the body distal surface, the spiral portion having a central axis at least substantially coextensive of the body central axis.

10. The apparatus of claim 9 further characterized in that the first means comprises a third needle that is an EKG electrode and has a spiral portion extending distally of the body distal surface, the third needle spiral portion having a central axis at least substantially coextensive of the body central axis.

11. The apparatus of claim 1 further characterized in that at least one of the second and third means comprises a first optical fiber having the respective distal surface.

12. The apparatus of claim 11 further characterized in that the optical fiber extends within the first needle.

13. The apparatus of claim 11 further characterized in that the fiber distal surface is substantially flush with the body distal surface.

14. The apparatus of claim 11 further characterized in that the fiber constitutes at least part of the light transmitting means.

15. The apparatus of claim 11 further

characterized in that the first means comprises a second needle mounted by the body and having a spiral portion extending distally of the body distal surface and has a distal terminal end portion extending within the fetus perfused tissue when the body is attached to the fetus, the spiral portion having a central axis that is at least substantively coextensive with the body central axis, the fiber extending within the first needle.

16. The apparatus of claim 15 further characterized in that the first needle has a portion that is linear extending distally of the body distal surface and has the first needle distal terminal end, the first fiber extending within the first needle.

17. The apparatus of claim 16 further characterized in that the second needle distal terminal end portion has an opening that opens to perfused tissue when the body is attached to the fetus and that the other of the second and third means comprises a second optical fiber extending within the second needle and having the respective distal surface adjacent to second needle opening.

18. The apparatus of claim 15 further characterized in that the first needle has a spiral portion extending distally away from the body distal surface, the first needle spiral portion having its central axis at least nearly coextensive with the body central axis and that the second needle distal terminal end portion has an opening that opens to perfused tissue when the body is attached to the fetus and that the other of the second and third means comprises a second optical fiber extending within the second needle and having the respective distal surface adjacent to second needle opening.

19. The apparatus of claim 18 further characterized in that one of the needles is an EKG electrode and that there is provided means electrically connected to the electrode for continuously monitoring the EKG.

20. Fetal monitoring apparatus for continuously monitoring oxygen saturation of functional arterial hemoglobin and monitoring the EKG of a fetus during labor and delivery, comprising a pulse oximeter having a light signal source, an EKG monitoring section, and a light receiver portion for determining the oxygen saturation from collected light that has passed through perfused fetal tissue, and a fetal probe having a longitudinal central axis and a distal end surface, first means mounted by the probe body to extend distally of the body distal surface and having an external spiral portion for penetrating fetal tissue to removably attach the probe body to the fetus and a distal terminal end to extend internally into the fetus and spaced from the skin, the first means including a first needle mounted by the probe body to extend distally of the body distal surface, having the spiral portion and defining an EKG electrode, second means extending through the fetal skin and into fetal perfused tissue and having a distal light collecting surface for collecting light after the light has passed through the adjacent perfused fetal tissue, third light means having a distal light transmitting surface for transmitting light to pass through the skin surface and perfused fetal tissue and then to the second means collecting surface, the second and third means extending within the probe body and having their distal surfaces sufficiently spaced from one another that the light has to travel through perfused tissue in traveling from the transmitting surface to the collecting surface when the body is attached to the fetus, at least one of

the second and third means distal surfaces being located internally of the fetal skin when the body is attached to the fetus, the third means including fourth means for transmitting visible light and fifth means for transmitting infrared light, means for connecting the fourth and fifth means to the light signal source to transmit the respective light to the third means distal surface, connecting means for connecting the second means to the light receiver portion to conduct the collected light thereto, and connecting means for connecting the EKG needle to the EKG monitoring section.

21. The apparatus of claim 20 further characterized in the light transmitting means has its distal end closely adjacent to the body distal surface and external of the fetal skin when the body is attached to the fetus.

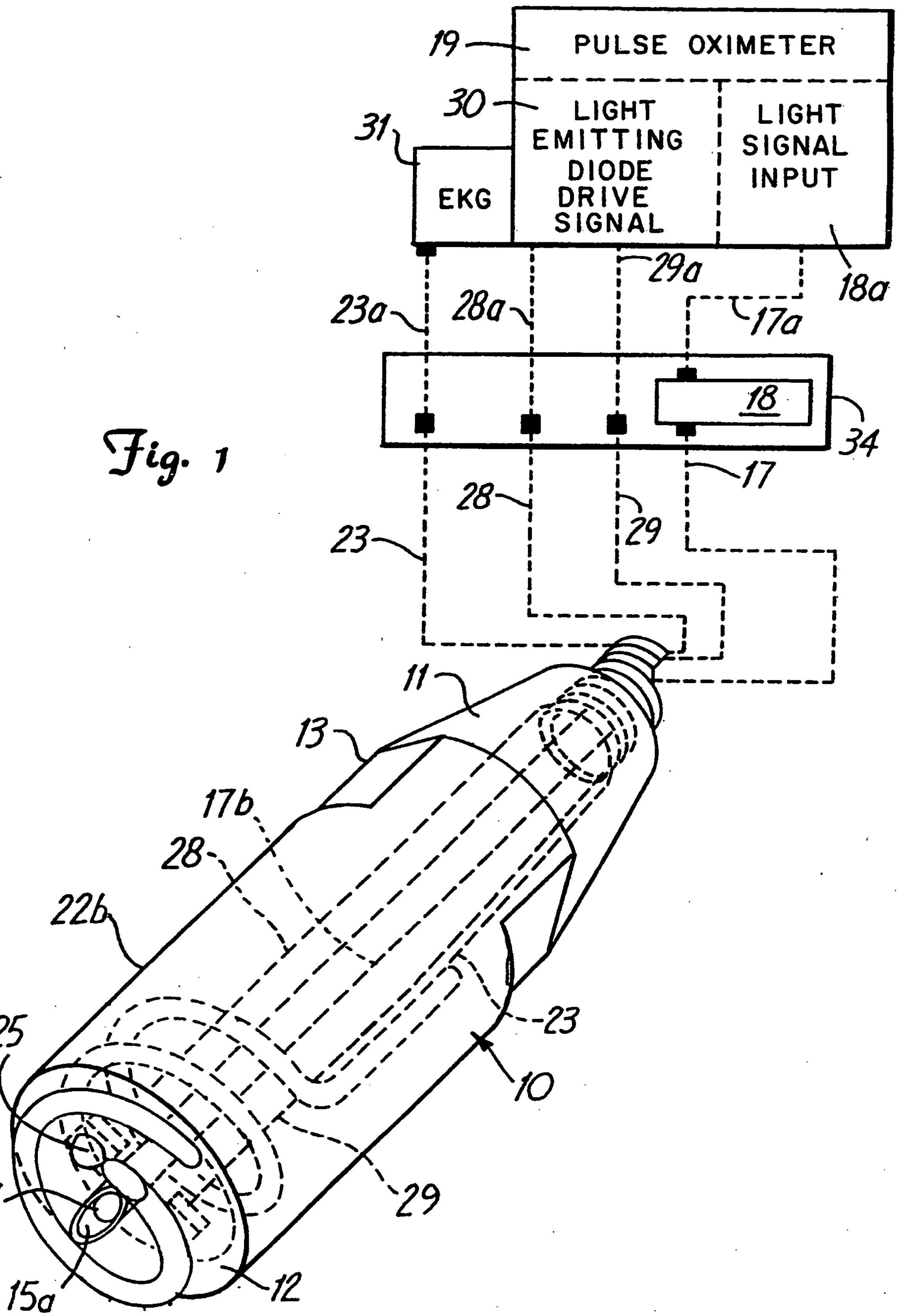
22. The apparatus of claim 20 further characterized in that each of the fourth and fifth means includes a light emitting diode.

23. The apparatus of claim 20 further characterized in that the first means includes a second needle having a hollow portion extending distally of the body distal surface and having an opening that opens to perfused tissue internally of the fetal skin when the body is attached to the fetus to have transmitted perfused light passed therethrough, the light collector means extending within the needle hollow portion and having its distal surface adjacent to the needle opening.

24. The apparatus of claim 24 further characterized in that the distal transmitting surface of the light transmitting means is adjacent to the body

distal surface and external of both of the fetal skin and the needle hollow portion.

25. The apparatus of claim 1 further characterized in that the distal transmitting surface is adjacent to the body distal surface and external of both of the needle and the fetal skin, and that the first means includes a spiral second needle extending distally of the body distal surface for monitoring EKG, and that the first needle is generally linear external of the body and has the light collecting means extending therein to extend distally remote from the body distal surface.


PULSE OXIMETER
LIGHT EMITTING DIODE DRIVE SIGNAL
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22b
23
10
25
29
17
15a
12

Fig. 1

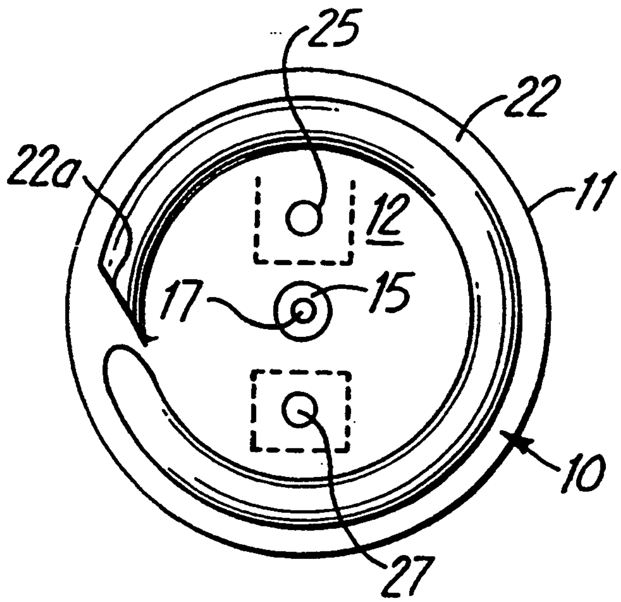


Fig. 2

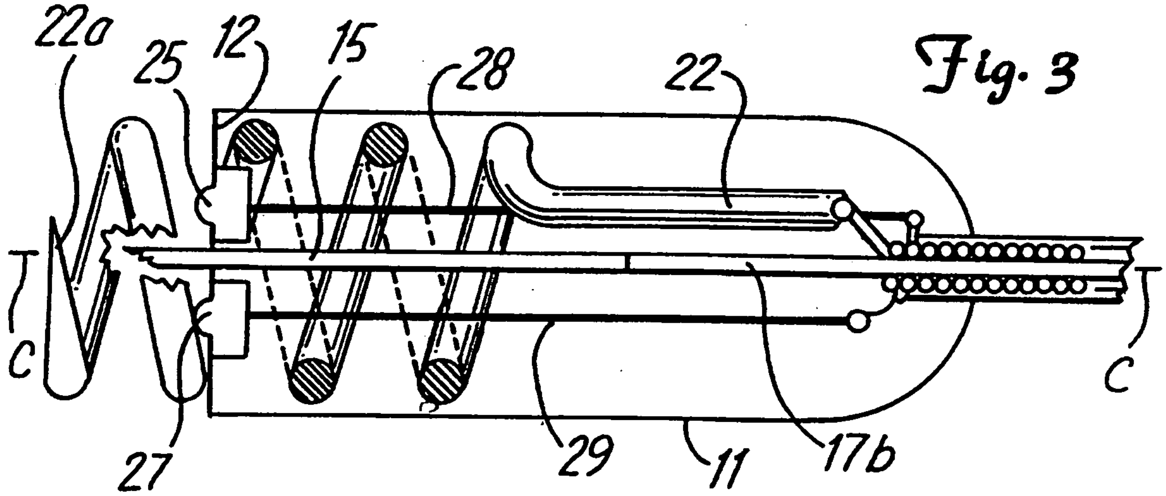


Fig. 3

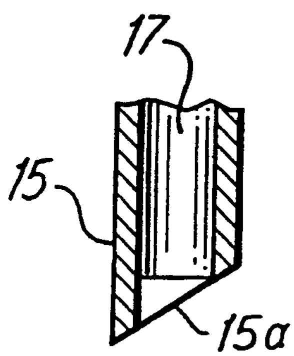


Fig. 4

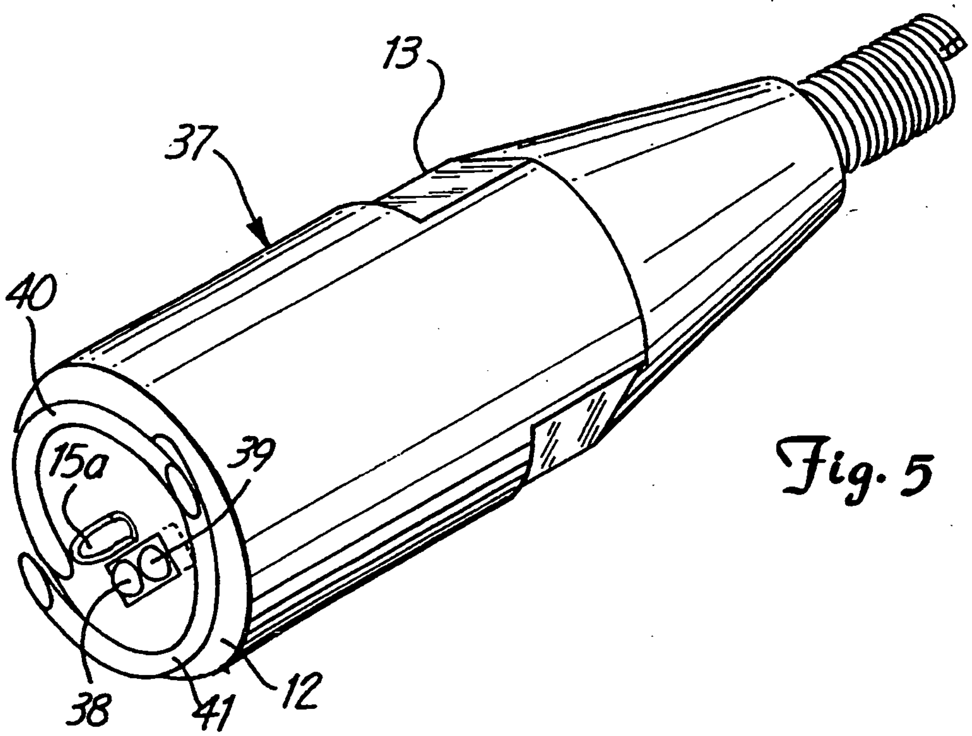
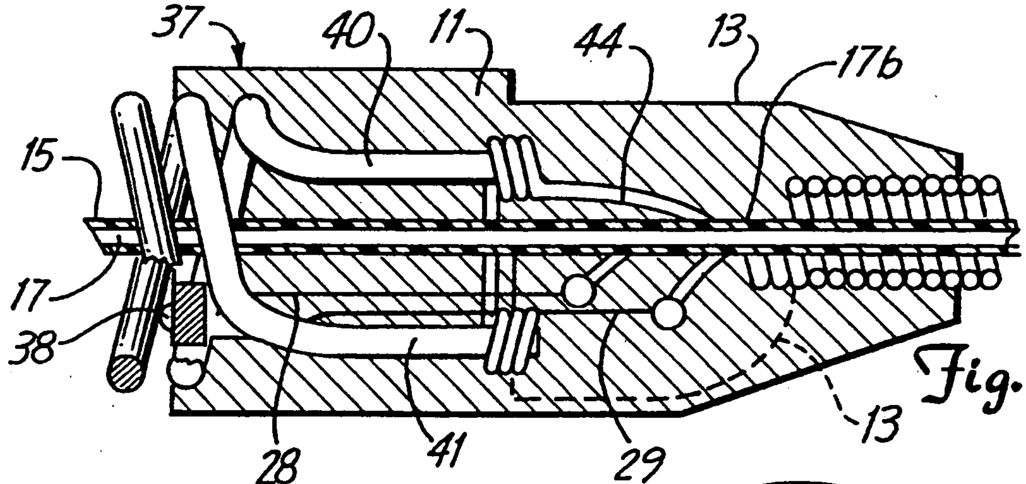


Fig. 5



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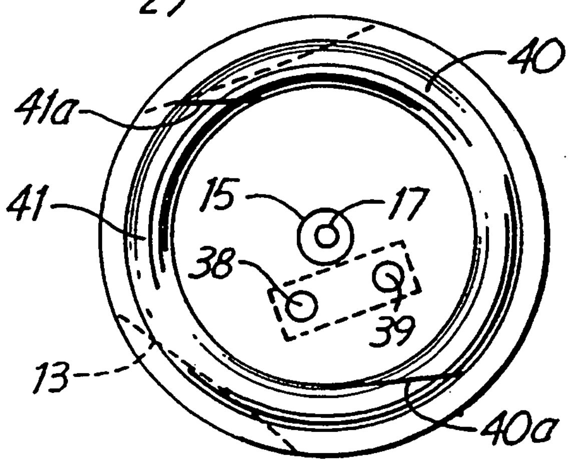

Fig. 7

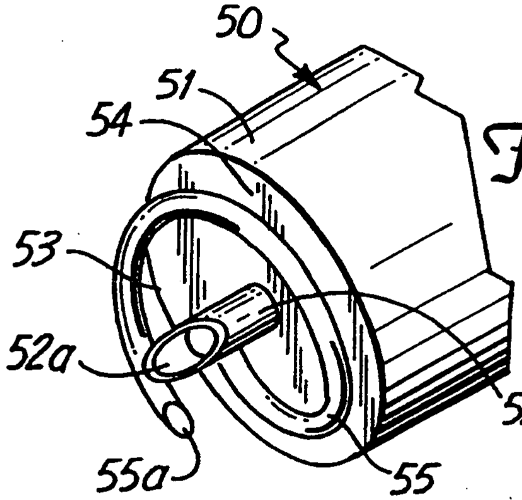

Fig.8

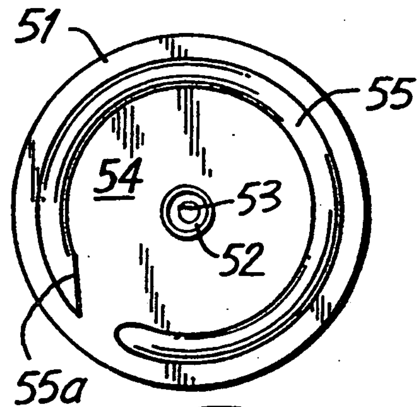

Fig.9

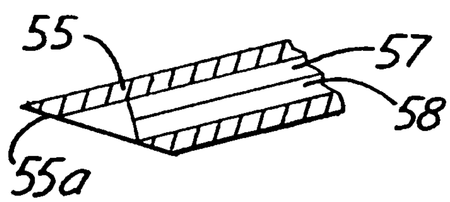

Fig. 10

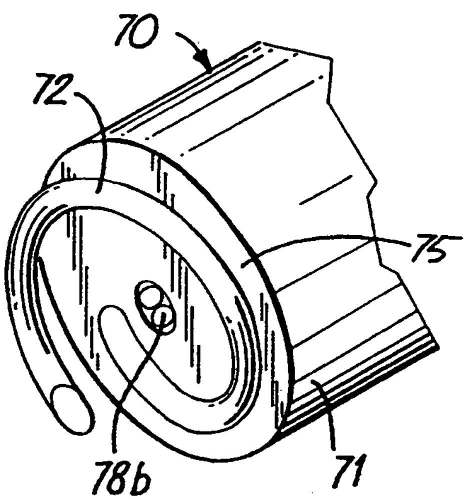

Fig.11

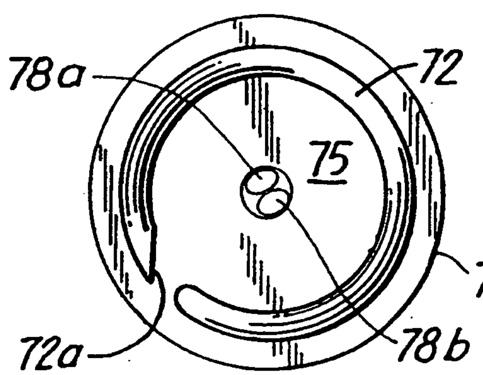

Fig. 12

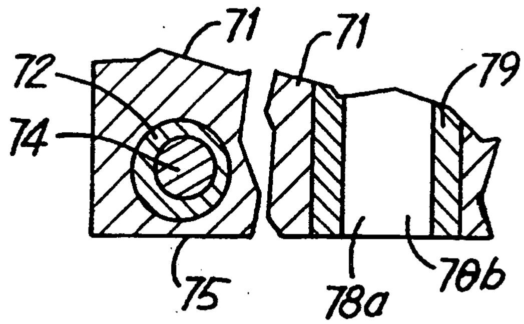

Fig. 13

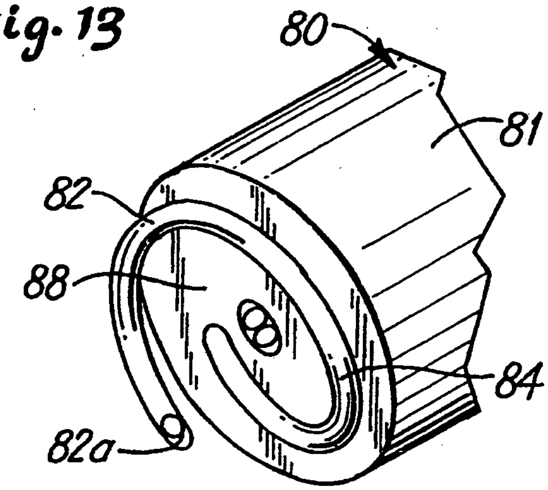

Fig. 14

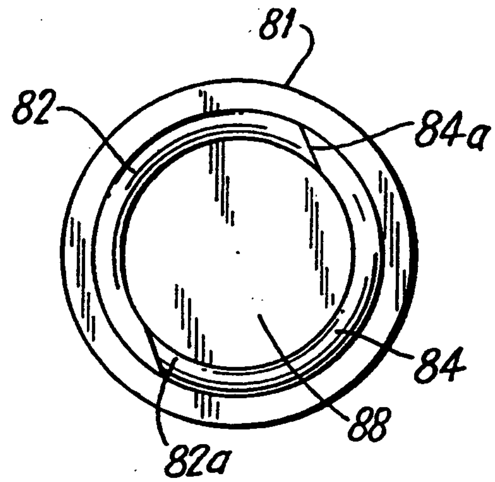

Fig. 15

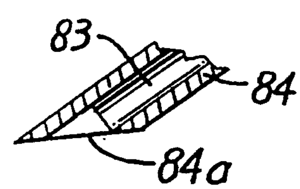

Fig. 17

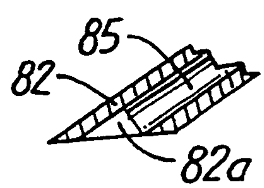

Fig. 16

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US91/03673

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC
IPC (5): A61B 5/00 A61B 5/042
U.S. CL: 128/633; 128/634; 128/642

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
U.S.	128/633,634,642

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
A	US, A, 4,658,825 (HOCHBERG) 21 April 1987, see entire document.	1,20
X Y	WO, A, 8,909,016 (BUSCHMANN) 05 october 1989, see entire document.	1-5,7-9,11-25 6,10
A	WO, A, 9,001,293 (GARDOSI) 22 February 1990 see entire document.	1,20

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
10 JULY 1991	29 JUL 1991
International Searching Authority	**Signature of Authorized Officer**
ISA/US	LEE S. COHEN